UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/701,295	11/03/2003	Nigel Benjamin	14-06	5269

23713 7590 04/30/2008

GREENLEE WINNER AND SULLIVAN P C
4875 PEARL EAST CIRCLE
SUITE 200
BOULDER, CO 80301

EXAMINER	
PAK, JOHN D	

ART UNIT	PAPER NUMBER
1616	

MAIL DATE	DELIVERY MODE
04/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/701,295	BENJAMIN ET AL.	
	Examiner	Art Unit	
	John Pak	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28 and 30-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28,30 and 31* is/are rejected.

7)☒ Claim(s) *32* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 28 and 30-32 are pending in this application.

Before turning to examination of these new claims on the merits, a review of effective filing date is again necessary because of its relevance on which prior art reference may be applied against the amended claims.

Amended claims 28 and 30-31 recite or read on the following feature:

28. (Currently amended) A dosage form for topical treatment of a bacterial, viral or fungal infection in a patient in need thereof, wherein said dosage form ~~comprising~~ is effective in killing infectious organisms on skin or treating bacterial, virus or fungal conditions while causing no significant inflammation, said dosage form consisting essentially of:

a pharmaceutically acceptable acidifying agent and a pharmaceutically acceptable carrier or diluent therefor, wherein said acidifying agent is an organic acid and wherein said acidifying agent is present in an amount sufficient to reduce pH at an environment of use to below 4, and

a pharmaceutically acceptable source of nitrite ions and a pharmaceutically acceptable carrier or diluent therefore, wherein said source of nitrite ions is an alkali metal or an alkaline earth metal nitrite and wherein said nitrite ions are in an amount effective when combined with said acidifying agent to treat said infection, ~~and~~

~~a pharmaceutically acceptable carrier or diluent therefor,~~

wherein said acidifying agent and said source of nitrite ions are separately disposed for admixture to release ~~nitrite ions~~ oxides of nitrogen at the intended environment of use ~~and wherein said acidifying agent is present in an amount sufficient to establish a pH at an environment of use below 4~~.

The claims therefore encompass unspecified suitable carriers or diluents, and the dosage form has separately disposed components. The instant specification shows that the scope of the carrier and diluent includes waxes (page 11, lines 3-10). However, a close review of related cases for which benefit of earlier filed application is claimed shows that only cream or ointment forms can have an effective filing date of the earliest claimed dates. In WO 95/22335 (publication of PCT/GB95/00338, filed on 2/17/1995), the following disclosure is found with respect to "disposed separately" feature (page 3):

> The pharmaceutical acceptable carrier or diluent may be an inert cream or ointment. In a particularly preferred form of the invention the acidifying agent and the source of nitrite ions or precursor therefor are separately disposed in said cream or ointment for admixture to release nitrite ions at the environment of use.

See also claim 5 of WO 95/22335:

> 5. A dosage form according to any preceding claim wherein the pharmaceutically acceptable carrier is disposed in an inert cream or ointment, and wherein said acidifying agent and said source of nitrite ions is separately disposed in a respective cream or ointment for admixture to release nitrate ions at the intended environment of use.

It is noted that 08/696,930 is a 371 of PCT/GB95/00338, which published as WO 95/22335, so that case provides no additional disclosure support.

Above discussion applies also to foreign priority applications with earlier filing dates than WO 95/22335. Relatedly, see the Examiner's comments regarding GB 9804469.6 in the Office action of 9/12/2005.

The Examiner therefore concludes that **at best** the earliest effective filing date for the currently claimed **subject matter of claims 28, 30-31 may be 3/1/1999**, the filing date of PCT/GB99/00605. This is because none of the earlier filed applications disclose the "disposed separately" feature with respect to any and all pharmaceutically acceptable carrier or diluent.

Without needing to determine at this time whether the effective filing date of the instant claims 28, 30-31 is 3/1/1999 (filing date of PCT/GB99/00605) or 6/11/1999 (filing date of parent case), further examination on the merits can continue now because the difference in those dates will not be material hereinbelow.

Effective filing date of claim 32 is 2/17/1995 or possibly earlier (going back to the GB foreign application filing dates, wherein it is not necessary at this time to make the determination of said earlier date since 2/17/1995 is sufficient for the purpose of this Office action).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 28 and 30-31 are rejected under 35 U.S.C. 102(e) as being anticipated by Seitz et al. (US 6,103,275).

Seitz et al. explicitly disclose a 1.5 wt% sodium nitrite gel and a 3.3 wt% ascorbic acid gel (column 9, lines 5-13). Two separate gels are disclosed (id.). The gels are to be combined to generate NO for topical treatments (see e.g., claim 12).

The claims are anticipated because every element of applicant's claims are expressly taught or necessarily encompassed. Applicant's amount language is noted with respect to the acid component, but 1-10 wt% ascorbic acid meets that feature (see specification page 9, lines 31-36 and previous claim 27, line 2). Hence, because Seitz et al. disclose 3.3 wt% ascorbic acid in a gel, this amount is sufficient to meet applicant's claim feature. Also, because Seitz's "dosage form" contains the same exact components as applicant's "dosage form," the same properties must necessarily be present. Hence, Seitz's disclosure meets applicant's feature, "for topical treatment of a bacterial, viral or fungal infection ... wherein said dosage form is effective for killing infectious organisms on skin or treating bacterial, virus or fungal conditions while causing no significant inflammation."

For these reasons, claims 28 and 30-31 are found to be anticipated.

Claim 32 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

U.S. Patent **7,048,951** to Seitz et al. is cited to further show the state of the art (see claims 23-30, 34-35). Applicant is advised of the potential for interference with respect to the two patents by Seitz et al., 6,103,275 and 7,048,951.

A minor misspelling is noted: in claim 1, line 11, "therefore" should be corrected as --- therefor --- .

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to John Pak whose telephone number is **(571)272-0620.** The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Johann Richter, can be reached on **(571)272-0646**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/John Pak/
Primary Examiner, Art Unit 1616